K023251

1. Summary of Safety and Effectiveness

DEC 0 4 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS for PEDIATRIC ARTERIAL CANNULA as required by section 807.92(c).

Submitter's Information

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Contact person:	Dana Olsen, Regulatory Affairs
Date of preparation:	November 11, 2002

Device name:

Trade Name:	Pediatric Arterial Cannula
Common/Usual name:	Pediatric Arterial Cannula
Classification name:	Cardiopulmonary bypass vascular cannula (21 CFR – 870.4210) Catheter Stylet (21 CFR – 870.1380) Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting (21 CFR –870.4290)

Predicate Device Name(s):

Jostra Pediatric Arterial Cannula - 510(k) no. K012617

Device Description

The Polystan pediatric arterial cannula is single-use, disposable, sterile and non-pyrogenic device. The cannula has a tapered wire reinforced PVC body with an open beveled distal tip. Three depth indicator marks are positioned at approximately 2 cm intervals from the distal tip. A stylet is incorporated to assist cannulation. The proximal cannula end terminates with either a $^{3}/_{16}$" or ¼" capped connector incorporating a female luer fitting. The cannulae range in size from 6 Fr. to12 Fr.

Intended Use

Pediatric Arterial Cannula is used to introduce blood and sterile solutions into the systemic circulation during pediatric extracorporeal circulation procedure.

Technological Characteristics Summary

The Polystan pediatric arterial cannulae have the same intended use as the predicate cannulae.

Biocompatibility testing of the Polystan Pediatric Arterial Cannulae was performed in accordance with the USP 23, USP 24 and the international standard ISO 10993 "Biological Evaluation of Medical Devices".

Performance and in-vitro testing included the blood pressure drop vs. flow rate test, blood cell damage test and the integrity test.

Conclusion:

The biocompatibility and performance test data demonstrated that the Polystan Pediatric Arterial Cannulae are substantially equivalent to the predicate device, the Jostra Pediatric Arterial Cannulae.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 04 2002

Polystan A/S
c/o Ms. Dana Olsen
Walgerholm 8,
3500 Værløse
Denmark

Re: K023251
Pediatric Arterial Cannula
Regulation Number: 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, and Tubing
Regulatory Class: Class II (two)
Product Code: 74 DWF
Dated: September 27, 2002
Received: September 30, 2002

Dear Ms. Olsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indication for Use

Statement of Indication for Use

The Pediatric Arterial Cannula is used to introduce blood and sterile solutions into the systemic circulation during pediatric extracorporeal circulation procedure.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K023351

Prescription Use X OR Over-The-Counter Use __